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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/605,783	06/27/2000	Jiangchun Xu	210121.427C16	4968

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07/08/2005

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EXAMINER

JOHANNSEN, DIANA B

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 07/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/605,783

Applicant(s)

XU ET AL.

Examiner

Diana B. Johannsen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 December 2004 and 15 April 2005.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 35,36 and 62-66 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 35,36 and 62-66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 December 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

5.00

FINAL REJECTION

1. This action is responsive to the Reply (including Drawings) filed December 20, 2004, and to the complying amendments to the specification filed April 15, 2005.

Applicant is reminded of MPEP 714.03, which states that the reply to a Notice of Non-Compliant Amendment "should consist of a corrected version of only that portion of the amendment which previously failed to comply with 37 CFR 1.121." The complete set of claims included in the amendment of April 15, 2005 (which was not required in response to the communication of March 18, 2005) was modified such that the status identifiers differ from the (correct) identifiers present in the claim set of December 20, 2004. Accordingly, the claim set of April 15, 2005 is non-compliant due to the use of incorrect status identifiers. However, as this claim set was not required to correct the issues of non-compliance raised in the communication of March 18, 2005, and as the application file includes a complying complete set of claims (the set of December 20, 2004), the claim set of April 15, 2005 has simply not been entered.

Accordingly, the documents under consideration are:

- the claim set of December 20, 2004;
- the specification amendments of April 15, 2005;
- the Drawings filed December 20, 2004; and
- the arguments of December 20, 2004.

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2. Claims 35, 62-63 and 65 have been amended, and claim 66 has been added. The claims now pending and under consideration are claims 35-36 and 62-66.

3. Applicants' amendments and arguments have been thoroughly reviewed, but are not persuasive for the reasons that follow. Any rejections not reiterated in this action have been withdrawn as being obviated by the amendment of the claims. **This action is FINAL.**

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Specification

5. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

It is noted that while Applicant included an amendment to the title in the (unentered) amendments to the specification filed December 20, 2004, this amendment was not included in the specification amendments filed April 15, 2005 in response to the Notice of March 18, 2005.

Claim Rejections - 35 USC § 112

6. Claims 35-36 and 62-66 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods for stimulating and/or expanding T cells using a peptide encoded by a particular subsequence of SEQ ID NO: 110 (the peptide disclosed as SEQ ID NO: 337), and for isolated T cell populations comprising T cells prepared by such methods, does not reasonably provide enablement for methods for stimulating and/or expanding T

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cells using the numerous other polypeptides encompassed by the claims, or for isolated T cell populations comprising T cells prepared by such methods. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims, for the reasons set forth below and in the Office action of September 20, 2004. **It is noted that Applicants' amendments to the claims (specifically, the addition of new claim 66) necessitated the inclusion of claim 66 in this rejection.**

With regard to the rejection set forth in the prior Office action of September 20, 2004, the response traverses the rejection on the following grounds. The response asserts that "Applicants' specification as filed describes numerous fragments of the polypeptide encoded by SEQ ID NO: 110 that have been experimentally determined to be capable of stimulating T cells." The response refers repeatedly to Example 12, arguing that the example describes the identification of several fragments encoded by SEQ ID NO: 110 that are "effective for stimulating" T cells. With regard to the "minimal 9-mer amino acid" encoded by SEQ ID NO: 110 that was demonstrated as giving a "strong response" in Example 12, the response argues that this fragments as well as "larger fragments comprising " it "were shown to be capable of stimulating human T-cells." The response urges that "the specification as filed describes and demonstrates numerous examples of polypeptides comprising at least a 9 amino acid fragment of the polypeptide by SEQ ID NO: 110, as claimed, that can be

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used in methods for stimulating human T-cells," and further that only routine screening would be required to identify additional fragments capable of doing so.

These arguments have been thoroughly considered but are not persuasive. It is noted that the claims as written require only a step of "contacting" with "T cells," not a step, e.g., of contacting with previously stimulated T cells that are specific for P501S (see also the discussion below with regard to the indefiniteness of the instant claims). In contrast, the example cited by Applicant as supporting of the enablement of the instant claims (Example 12) describes the screening of a very specific, particular type of T cell (T cells already stimulated by P501S) to determine which fragments of P501S are reactive with such T cells (and which therefore constitute reactive epitopes of the protein). Thus, while Applicants' arguments might be persuasive with respect to claims to a method such as that performed in Example 12, they are not pertinent to the invention of the instant claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

With further regard to claim 66, it is again noted that the specification exemplifies only a single particular peptide (SEQ ID NO: 337) contained within SEQ ID NO: 113 that actually stimulates T cells (as is required by the claim as written). While one of skill in the art would in fact expect that T cells stimulated with this particular peptide would react with at least some larger fragments containing the peptide (depending on the conformation of such fragments, accessibility of the epitope, etc.), it is again noted that the instant claim is not

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drawn to such methods, but to a method in which any T cell is contacted with "at least one antigen presenting cell that expresses or is pulsed with a polypeptide" that comprises SEQ ID NO: 337 (i.e., the claim is not limited either to the particular peptide of SEQ ID NO: 337, or to the use of a population of T cells stimulated with that peptide). Thus, this claim also lacks enablement for the reasons of record.

As it would require undue experimentation to make and use Applicants' invention in a manner reasonably commensurate with the claims, for the reasons given above and in the Office action of September 20, 2004, this rejection is maintained.

**THE FOLLOWING ARE NEW GROUNDS OF REJECTION NECESSITATED
BY APPLICANTS' AMENDMENTS:**

7. Claims 35-36 and 62-66 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 35-36 and 62-66 are indefinite because it is unclear whether the claims are drawn to methods for "stimulating and/or expanding" a population of T cells that is "specific for an amino acid sequence encoded by SEQ ID NO: 110," and/or whether the claims encompass methods in which naïve T cells are first activated (so as to become "specific for" an amino acid sequence encoded by SEQ ID NO: 110), and then stimulated and/or expanded. The language of the preambles of claims 36, 63, and 66 is ambiguous: it is not clear whether the recitation "method for stimulating and/or expanding T cells specific for an amino

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acid sequence encoded by SEQ ID NO: 110" does or does not limit the types of T cells employed in the claimed methods. Further, with regard to claim 35 and claims dependent therefrom, it is again noted that while the single method step of "contacting" appears to be sufficient only to stimulate and/or expand previously activated T cells, the claims recite only the use in this method step of "T cells" (rather than, e.g., "T cells specific for an amino acid sequence encoded by SEQ ID NO: 110"). Accordingly, it is unclear as to what is required to meet the objectives of the claims, and, with respect to claim 35 and claims dependent therefrom, it further appears that the step recited in the claim may be insufficient to meet this objective. While Applicants' traversal of the prior rejection of claims 35-36 and 62 related to the use of the language "specific for a prostate-specific protein" is noted, Applicants' statements and arguments regarding what is known by one of skill in the art and disclosed in the specification with respect to T cells does not address the specific concerns raised herein about the ambiguities of the present claims. Accordingly, clarification is required.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory

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action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

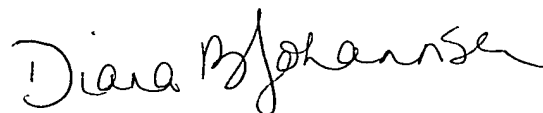
9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 571/272-0744. The examiner is currently on maternity leave, but is normally in the office on Wednesdays and will respond to telephone inquiries at that time. Alternatively, inquiries requiring immediate attention may be directed to the examiner's supervisor at the number given below.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached at 571/272-0745. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR

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system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, reading "Diana B. Johannsen". The signature is written in a cursive style with a large, stylized "D" and "J".

Diana B. Johannsen
Primary Examiner
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July 6, 2005